Article - Health - General

[Previous][Next]

§21–224.

(a) (1) A new drug is not subject to the requirements of § 21-223 of this subtitle if it is exempted by a rule or regulation adopted under this section.

(2) This section does not require any clinical investigator to submit directly to the Secretary any report on the investigational use of a drug.

(b) The Secretary shall adopt rules and regulations to exempt from the requirements of § 21-223 of this subtitle any drug that is intended only for investigational use by experts who are qualified by scientific training and experience to investigate the safety and effectiveness of the drug. In addition to any other conditions that may be imposed for the protection of the public health, the rules and regulations may require as a condition for the exemption of a drug that:

(1) Before any clinical testing of a new drug is undertaken, the manufacturer of the drug or the sponsor of the investigation of the drug submit to the Secretary reports of preclinical tests of the drug, including tests on animals, that are adequate to justify the proposed clinical testing;

(2) The manufacturer of a new drug that is proposed to be distributed to investigators for clinical testing or the sponsor of the investigation obtain a signed agreement from each investigator who is involved that:

(i) The patients to whom the drug is administered will be under that investigator's personal supervision or under the supervision of an investigator who is responsible to that investigator; and

(ii) The investigator will not supply the drug to any other investigator, or to any clinic, for administration to a human being; and

(3) The manufacturer of a new drug or the sponsor of the investigation of the drug keep records of, and make reports to the Secretary of, the information obtained from the investigational use of the drug, including analytical reports by investigators, as the Secretary finds will assist in the evaluation of the safety and effectiveness of the drug if an application for the drug is filed under § 21-223 of this subtitle.

(c) (1) When adopting a rule or regulation that requires the submission of information under this subsection, the Secretary shall consider the professional ethics of the medical profession and the interests of patients.

(2) Any rule, regulation, or order under this section shall provide that if any person to whom the rule, regulation, or order applies requests it, and if the Secretary considers it to be appropriate, the person may examine any similar information that is obtained by the Secretary concerning the drug.

(d) (1) Any rule or regulation adopted under § 355(i) of the federal act automatically shall be a rule or regulation of this State, as provided in § 21-241 of this subtitle.

(2) However, the Secretary may adopt a rule or regulation under this section even if it is not in accord with the rules and regulations adopted under the federal act.

[Previous][Next]